

REMARKS

Status of the Claims

Claims 1, 3-10, and 18-20 are pending, with claims 1, 5, 6, and 18 being independent. Claims 2 and 11-17 have been canceled without prejudice to or disclaimer of the subject matter contained therein, as being directed to non-elected subject matter. Applicants have no intention of abandoning any non-elected subject matter, and Applicants expressly reserve the right to file one or more continuation and/or divisional applications directed to non-elected subject matter. Without conceding the propriety of the rejections, claims 1, 4 - 10, and 19 have been amended to even more clearly recite and distinctly claim Applicant's invention and to pursue an early allowance. Support for the amendments can be found in the original claims, as well as throughout the specification. Therefore, no new matter has been added.

Applicants initially would like to thank the Examiner for indicating that the claims contain allowable subject matter.

Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections in view of the foregoing amendments and the following remarks.

Claim Rejections under 35 U.S.C. § 112

Claims 5 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants have amended claims 5 and 19, thus obviating the rejection. In particular, claim 5 has been amended to remove the term "preferably" and claim 19 has been amended to correct the dependency.

Election/Restriction

Based on Applicants' previous election of species, the Examiner identified the following generic group for examination in the present application:

Compounds of Formula (I) wherein:

- (a) X is hydroxyl;
- (b) R¹ and R² are independently hydrogen or hydroxyl; and
- (c) Z is a group of the formula -M-Q^b-D' wherein

M is selected from the group consisting of $-\text{CH}_2\text{OC}(\text{O})-$ and $-\text{CH}_2\text{CH}_2\text{C}(\text{O})-$;

Q^b is $[\text{E}-(\text{F}^*)_n\text{G}]$ - wherein E is oxygen, G is $-\text{C}(\text{O})-$ and F is as defined by claim 8; and

D' is a GABA analog moiety as defined by claim 5, wherein $\text{R}^{3'}$ is a bond linking the GABA analog moiety to Q^b and $\text{R}^{11'}$ is selected from the group consisting of carboxylic acid, carboxylic amide, and carboxylic ester.

Applicants respectfully traverse the Examiner's dissection of their invention into "inventive groups" as defined by the Examiner, and thus reserve the right to Petition the Commissioner requesting removal thereof. Applicants note that their previous election of species identified by compound 230 was for the purposes of searching only.

Through the identification of this generic group for examination, the Examiner is requiring the dissection of Applicants' invention into numerous groups, and the Examiner, rather than the Applicants, is identifying what Applicants regard as their invention. Accordingly, the election requirement coupled with the generic group, as determined by the Examiner, necessitates the dissection of Applicants' invention into numerous groups and constitutes a refusal on the part of the Office to examine the claim that Applicants believe to best represent their invention.

Applicants submit that it is improper for the Office to refuse to examine that which Applicants regard as their invention unless the subject matter of the claims lacks unity of invention. Specifically, in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978), the court articulated the general proposition that:

[A]n applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Id. at 331. (Emphasis in original).

In view of the above and similar case law, the Patent Office has set forth a general policy regarding restriction of Markush-type claims in MPEP 803.02. According to the general policy as articulated in the MPEP, “since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334, it is *improper* for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).” (MPEP 803.02, emphasis added). Unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature.

Applicants note that in order to expedite prosecution the claims have been amended as provided above. Applicants respectfully assert that the presently claimed subject matter clearly exhibits unity of invention. With regard to a common utility, the compounds of the present claims use the bile acid transport system to provide sustained systemic concentration of orally delivered GABA analogs. With regard to a substantial structural feature, the compounds of the present claims all comprise a bile acid moiety linked to a GABA analog moiety. Applicants submit that the precise structure of the linker group connecting the bile acid moiety and the GABA analog moiety is not critical. According to the present invention, it is only necessary that the linking group be cleavable under physiological conditions to release the GABA analog moiety or active metabolite thereof into the systemic blood circulation. Therefore, Applicants respectfully submit that the compounds of the present claims clearly evidence unity of invention.

In view of the amended claims and the policy regarding restriction of Markush-type claims as provided above, Applicants submit that it is improper for the Office to refuse to examine the presently claimed invention since the presently claimed subject matter clearly evidences unity of invention.

Applicants also respectfully remind the Examiner that even where a provisional election of a single species is proper prior to examination on the merits, following election the Markush-type claim should be examined fully with respect to the elected species and further to the extent necessary to determine patentability. (MPEP 803.02).

The MPEP requires that should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim *will be extended* to non-elected species. (*Id.*, emphasis added).

Applicants note that they have amended the claims as provided above to expedite prosecution and thus, they are willing to file one or more divisional applications directed to the non-elected embodiments. However, Applicants respectfully traverse any further dissection of their invention into "inventive groups" as defined by the Examiner, and Applicants respectfully submit that as unity of invention exists in the presently claimed compounds, it is improper for the Office to refuse to examine the invention as claimed.

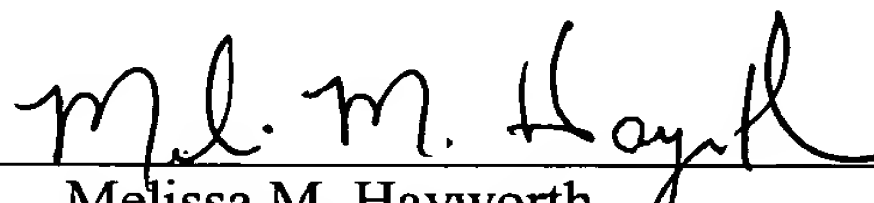
Conclusion

Without conceding the propriety of the rejections, the claims have been amended, as provided above, to highlight particularly preferred embodiments of Applicants' invention and to pursue an early allowance.

In view of the foregoing remarks, reconsideration of the claims and allowance of the subject application is earnestly solicited. The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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